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PERREIRA, MELISSA JEAN	
ART UNIT	**PAPER NUMBER**
1618	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	03/19/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/719,530	KLEIN ET AL.	
	Examiner	Art Unit	
	Melissa Perreira	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 November 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-29* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-29* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *8/26/04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 112

1. Claims 1-12 and 15-23 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the methods of marking and modifying anatomical sites, such as blood vessels, a site of a breast or colon biopsy, an epidermal site, the swallowing system, the lower esophageal sphincter, the urinary and anal sphincters of a patient with a tissue modifying material does not reasonably provide enablement for the methods of marking and modifying every anatomical site of a patient, such as into the eye or brain, etc. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

Attention is directed to In re Wands, 8 USPQ2d 1400 (CAFC 1988) at 1404 where the court set forth the eight factors to consider when assessing if a disclosure would have required undue experimentation. Citing Ex parte Forman, 230 USPQ 546 (BdApls 1986) at 547 the court recited eight factors:

1) the quantity of experimentation necessary,
2) the amount of direction or guidance provided,
3) the presence or absence of working examples,
4) the nature of the invention,
5) the state of the prior art,
6) the relative skill of those in the art,
7) the predictability of the art, and
8) the breadth of the claims.

The instant specification fails to provide guidance that would allow the skilled artisan to practice the instant invention without resorting to undue experimentation, as discussed in the subsections set forth hereinbelow.

The nature of the invention, state of the prior art, relative skill of those in the art, and the predictability of the art

The claimed invention relates to the methods of marking and modifying anatomical sites with a tissue modifying material, which encompasses any anatomical site of a subject. While the relative skill in the art is high with regard to modifying a blood vessel with an embolization material, such as microparticles in a carrier fluid it would be it is improbable that the methods of modifying or marking an anatomical site would translate clearly into methods of modifying or marking the eye or brain of a subject. Given the great diversity between various anatomical sites (structure, function, etc.) it would not be expected that the methods of modifying or marking all anatomical sites would be accomplished in the same fashion and would not be global methods for all anatomical sites.

Thus, a considerable amount of empirical testing is required, with no *a priori* expectation of success being present, before the methods of modifying or marking an anatomical site with the tissue modifying material would be successful or appropriate.

The breadth of the claims

The claims are very broad and inclusive of "anatomical sites" generally, which includes all anatomical sites. Clearly, the methods are only used to modify or mark an anatomical site, such as a blood vessel, site of a biopsy and the lower esophageal, urinary or anal sphincter of a patient.

The amount of direction or guidance provided and the presence or absence of working examples

The specification provides no direction for ascertaining, *a priori*, which anatomical sites can be modified or marked, except those stated above as there are no working examples of the use of the tissue modifying material in a subject.

4. The quantity of experimentation necessary

Applicants fail to provide the guidance and information required to ascertain which anatomical sites, except for those listed above, the claimed tissue modifying material will be effective for modifying or marking without resorting to undue experimentation. Applicant's limited disclosure of anatomical sites is not sufficient to justify claiming all anatomical sites broadly. Such methods of modifying or marking anatomical sites, having various structures and functions, would no doubt require undue experimentation.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

3. Claims 1-8,12,15 and 17-27 are rejected under 35 U.S.C. 102(b) as being anticipated by Lawin et al. (US 5,451,406).

4. Lawin et al. (US 5,451,406) teaches of biocompatible carbon-coated microbeads or microparticles, such as titanium/alloys, gold, silver,etc. (column 2, lines 12-17) from about 100 microns (column 2, lines 2-4) that are used for the method of tissue augmentation. The microparticles of the disclosure encompass the microparticles of the instant claims as the microparticles of the instant claims can be about 90 microns or less than about 100 microns which can be about 100 microns. The carbon-coated microparticles of the disclosure are used in an injectable composition including a lubricative carrier for the particles (column 1, line 6; column 2, lines 21-22 and 40). The carbon coating allows for a smooth surface to enhance the passage of the particles through an injection needle, provides strength, resistance to breakdown or corrosion and the durability of the carbon coating insures the effective, long term functioning of the particles in tissue augmentation at the site of injection (column 3, lines 35-41). Although the intended use of the microparticles does not afford any patentable weight, the method of augmenting a desired tissue site, such as the urinary sphincter muscle (claims 20-22) with the microparticles of the disclosure would inherently also modify the tissue and cause a marking to the tissue, such as a bump. The miroparticles were administered to dogs via periurethral injection (column 4, lines 65+). In regards to the size range of the microparticles, it is noted that "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955).

5. Claims 1- 8,10-12,15 and 17-27 are rejected under 35 U.S.C. 102(b) as being anticipated by Lawin et al. (US 5,792,478).

6. Lawin et al. (US 5,792,478) teaches of biocompatible carbon-coated microbeads or microparticles from about 100 microns (column 3, lines 45-48; column 2, line 58) that are used for the method of tissue augmentation. The microparticles of the disclosure encompass the microparticles of the instant claims as the microparticles of the instant claims can be about 90 microns or less than about 100 microns which can be about 100 microns. The carbon-coated microparticles of the disclosure are used in an injectable composition including a lubricative carrier for the particles (column 2, lines 52-56;). The carbon coating allows for a smooth surface to enhance the passage of the particles through an injection needle, provides strength, resistance to breakdown or corrosion and the durability of the carbon coating insures the effective, long term functioning of the particles in tissue augmentation at the site of injection (column 4, lines 50-55). Although the intended use of the microparticles does not afford any patentable weight, the method of augmenting a desired tissue site with the microparticles of the disclosure would inherently also modify the tissue and cause a marking to the tissue, such as a bump or bulking (column 6, line 15). Desired tissue site may include the anal sphincter muscle (claims 13,15-17), the upper gastrointestinal tract (column 6, lines 30-35) and the cardiac orifice of the stomach which opens into the esophagus and assists in overcoming gastric fluids refluxing into the esophagus. The miroparticles were administered to dogs via implant (column 6, line 38). In regards to the size range of the microparticles, it is noted that "[W]here the general conditions of a claim are disclosed in

the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955).

7. Claims 1-8,11,12,15 and 17-27 are rejected under 35 U.S.C. 102(e) as being anticipated by Klein (US 6,277,392).

8. Klein (US 6,277,392) teaches of an injectable biocompatible composition of carbon particles and a lubricative fluid where the microparticles range in size from 90 to 1000 microns. The method of augmenting a tissue site thereby correcting a defect, filling a void or strengthening a support structure is also disclosed (column 2, lines 43-55). The microparticles of the disclosure encompass the microparticles of the instant claims as the microparticles of the instant claims have a major dimension of less than about 100 microns or about 90 microns which includes 100 microns. The high strength, resistance to breakdown or corrosion, and durability of the carbon insures the effective, long term functioning of the particles in tissue augmentation at the site of injection (column 4, lines 20-23). Although the intended use of the microparticles does not afford any patentable weight, the method of augmenting a desired tissue site with the microparticles of the disclosure via injection would inherently also modify the tissue and cause a marking to the tissue, such as a bump or bulking (column 5, line 22). Desired tissue site may include the anal sphincter muscle (claims 9,11-14), the upper gastrointestinal tract and the cardiac orifice of the stomach which opens into the esophagus and assists in overcoming gastric fluids refluxing into the esophagus (column 5, lines 9, 28 and 37). In regards to the size range of the microparticles, it is

noted that "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955).

9. Claims 1-9,13-15 and 17-29 are rejected under 35 U.S.C. 102(e) as being anticipated by Klein (US 6,355,275B1).

10. Klein (US 6,355,275B1) teaches of an injectable, embolization material comprising a biocompatible carbon coated microparticle, such as gold, silver, stainless steel (column 3, lines 44-46), from about 100 microns to 1000 microns in a biocompatible carrier and the use of the microparticles for the method of embolization (column 2, lines 41-49). The microparticles may include radionuclide complexes, radioactive metal isotopes, etc. (column 8, lines 9-24) for use as contrast agents. The method for embolization includes delivery of the microparticles to a blood vessel via injection or canula (column 3, lines 20-22; column 5, lines 8 and 9). The microparticles of the disclosure encompass the microparticles of the instant claims as the microparticles of the instant claims have a major dimension of less than about 100 microns or about 90 microns which includes 100 microns. The high strength, resistance to breakdown or corrosion, and durability of the carbon insures the effective, long term functioning of the particles in tissue augmentation at the site of injection (column 9, lines 40-44). Although the intended use of the microparticles does not afford any patentable weight, the method of embolization with the microparticles of the disclosure via injection would inherently also modify the tissue and cause a marking to the tissue such as a

bump. In regards to the size range of the microparticles, it is noted that "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955).

11. Claims 1-9 and 15-27 are rejected under 35 U.S.C. 102(e) as being anticipated by Klein (US 6,394,965).

12. Klein (US 6,394,965) teaches of biocompatible carbon-coated microparticles, such as gold, titanium, silver, etc. (column 2, lines 31-40), from about 100 microns to 1000 microns that are used for the method of tissue marking (column 2, lines 10-22). The microparticles of the disclosure can be delivered via injection with a syringe in a carrier fluid (column 2, lines 41-42 and 51-52). The methods of marking tissue, such as the site of a breast biopsy involves injecting the microparticles to the desired site (column 3, lines 52-56; column 7, line 27). The microparticles may also include radionuclide complexes, radioactive metal isotopes, etc. for use as contrast agents (column 2, lines 46+). The microparticles of the disclosure encompass the microparticles of the instant claims as the microparticles of the instant claims have a major dimension of less than about 100 microns or about 90 microns which includes 100 microns. Although the intended use of the microparticles does not afford any patentable weight, the method of marking a tissue with the microparticles of the disclosure via injection would inherently also modify the tissue and cause a marking to the tissue such as a bump. In regards to the size range of the microparticles, it is noted

that "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955).

Claim Rejections - 35 USC § 103

13. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

14. Claims 1-9,12-15 and 17-29 are rejected under 35 U.S.C. 103(a) as being unpatentable over any one of Lawin et al. (US 5,451,406) in view of Greff et al. (US 5,851,508).

15. Lawin et al. (US 5,451,406) discloses biocompatible carbon-coated microbeads or microparticles, such as titanium/alloys, gold, silver,etc (column 2, lines 12-17) from about 100 microns (column 2, lines 2-4) that are used for the method of tissue augmentation as well as that stated above. Lawin et al. (US 5,451,406) does not disclose the carbon-coated microparticles also including a biologically active agent.

16. Greff et al. (US 5,851,508) discloses injectable compositions for embolization and the method of embolization (column 4, lines 14-15). The compositions comprise metal (gold, platinum) microparticles of about 10 microns, a biocompatible carrier fluid (column 5, lines 7-16) and a biologically active agent, such as a chemotherapeutic agent, anti-inflammatory agent, etc (column 6, lines 65+). The method of embolization

involves (column 5, lines 66+) administration of the injectable microparticle compositions via catheter (column 6, lines 17-20).

17. At the time of the invention it would have been obvious to one ordinarily skilled in the art to include a biologically active agent into the biocompatible carbon-coated microparticles of Lawin et al. (US 5,451,406) as the microparticles of Greff et al. (US 5,851,508) may consist of the same material (i.e. gold) as that of Lawin et al. The inclusion of a biologically active agent or medicament allows for delivery of the medicament right to the site of interest, such as a vascular site. The method of embolization of Greff et al. encompasses the method of augmentation of Lawin et al. as embolization in fact is an augmentation of a vascular site. The augmentation may be to prevent/control bleeding or to ablate diseased tissue (Greff et al., column 6, lines 57-64). Although the gold microparticles of Greff et al. are not carbon coated it would be obvious to do so since the carbon coating allows for a smooth surface to enhance the passage of the particles through an injection needle, provides strength, resistance to breakdown or corrosion and the durability of the carbon coating insures the effective, long term functioning of the particles in tissue augmentation at the site of injection (Lawin et al., column 3, lines 35-41).

18. Claims 1- 8,10-12,15 and 17-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ersek et al. (US 5,336,263) in view of Lawin et al. (US 5,451,406) or Lawin et al. (US 5,792,478).

19. Ersek et al. (US 5,336,263) discloses biocompatible fluid vehicle containing micro-implants for the method of treating urological disorders/soft tissue augmentation via injection into the bladder-urethral junction, the esophageal-gastric junction and the gastric-pyloric junction (column 3, lines 9-13; column 12, lines 40-41; claim 18). The microparticles are between 80 to 100 microns and may be composed of metal, such as stainless steel (column 4, line 63; column 6, lines 4-8). Ersek et al. does not disclose that the microparticles are carbon coated.

20. Lawin et al. (US 5,451,406) or Lawin et al. (US 5,792,478) disclose that stated above.

21. At the time of the invention it would have been obvious to carbon coat the microparticles of Ersek et al. (US 5,336,263) since both Lawin et al. (US 5,451,406) and Lawin et al. (US 5,792,478) disclose that the carbon coating allows for a smooth surface to enhance the passage of the particles through an injection needle, provides strength, resistance to breakdown or corrosion and the durability of the carbon coating insures the effective, long term functioning of the particles in tissue augmentation at the site of injection.

Double Patenting

22. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140

F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

23. Claims 1-8,11,15 and 17-23 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1,7,13-15,26,28-32 of copending Application No. 10/280,163. Although the conflicting claims are not identical, they are not patentably distinct from each other because the method of modifying a lower esophagus of a patient, such as the lower esophageal sphincter of copending Application No. 10/280,163 encompasses the methods of modifying and marking the lower esophageal sphincter of the instant claims. The microparticles of copending Application No. 10/280,163 have an exposed surface of carbon as do the microparticles of the instant claims and both are delivered via injection in a carrier solution.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

24. Claims 1-9,12-15 and 17-23 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims

30,32,35,37-39,42,43 and 46-48 of copending Application No. 10/446,647. Although the conflicting claims are not identical, they are not patentably distinct from each other because the methods of treating a desired site within a physiological system (i.e. embolization and tissue modification) of the copending Application No. 10/446,647 encompass the methods of embolization, modifying and marking of an anatomical site of a patient of the instant claims. The magnetic microparticles of copending Application No. 10/446,647 have an exposed surface of carbon with includes a biologically active agent as do the microparticles of the instant claims and both are delivered via injection in a carrier solution. The species of magnetic microparticles of copending Application No. 10/446,647 anticipates the genus of microparticles of the instant claims.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

25. Claims 24-29 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1,10,12,18-20,22 and 23 of copending Application No. 10/446,647. Although the conflicting claims are not identical, they are not patentably distinct from each other because the magnetic microparticles of copending Application No. 10/446,647 have an exposed surface of carbon with includes a biologically active agent as do the microparticles of the instant claims and both are delivered via injection in a carrier solution. The species of magnetic microparticles of copending Application No. 10/446,647 anticipates the genus of microparticles of the instant claims.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

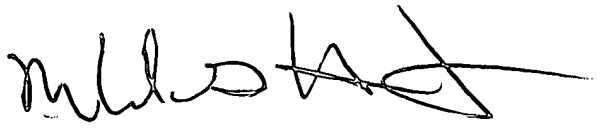
No claims are allowed at this time.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Melissa Perreira whose telephone number is 571-272-1354. The examiner can normally be reached on 9am-5pm M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Hartley can be reached on 571-272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

MP
March 12, 2007



MICHAEL G. HARTLEY
SUPERVISORY PATENT EXAMINER